Extending the Application of Tubeless Percutaneous Nephrolithotomy

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OBJECTIVES Tubeless percutaneous nephrolithotomy (PCNL) has been successfully performed in selected patients. We assessed its applicability for use without imposing preoperative restrictions.

METHODS The study consisted of a prospective and consecutive series of 126 patients. Tubeless PCNL was performed when perforation, residual stones, and significant bleeding had been intraoperatively excluded by fluoroscopy, nephroscopy, and hemodynamic assessment. Staghorn stones, supracostal and/or multiple access, anatomic anomalies, previously operated kidneys, solitary kidneys, and operative time were not considered contraindications. The demographic, clinical, and intraoperative and postoperative data were statistically analyzed.

RESULTS Using this protocol, we performed 66 (52%) tubeless and 60 (48%) regular PCNLs. The average patient age (54 years versus 52 years), stone burden (924 versus 1044 mm^2), operative time (116 versus 130 minutes), complication rate (9% versus 13%), hemoglobin decrease (1.2 versus 1.1 mg/dL), and immediate stone-free rate (92% versus 90%) were similar for the tubeless and regular PCNL groups, respectively ($P > 0.05$). The reasons for performing standard PCNL were an expected second-look procedure (n = 35, 58%), an impression of active bleeding (n = 16, 27%), significant extravasation (n = 5, 8%), and suspected hydrothorax (n = 4, 7%). The overall transfusion rate was 3%. The average analgesia requirement (pethidine HCL) was 0.4 and 1.2 mg/kg ($P < 0.01$), the median hospital stay was 1 and 4 days ($P < 0.0001$), and the median back-to-work time was 7 and 15 days ($P < 0.001$) for the tubeless and regular PCNL groups, respectively.

CONCLUSIONS The results of our study have shown that tubeless PCNL can be safely and effectively performed based on intraoperative factors, without preoperative contraindications. Compared with the standard procedure, tubeless PCNL was associated with reduced postoperative pain, hospital stay, and recovery time. UROLOGY 70: 412–417, 2007. © 2007 Elsevier Inc.

The clinical experience gained with large series of patients, as well as the refinements in techniques and instrumentation, has contributed to the improved efficacy and decreased morbidity of percutaneous nephrolithotomy (PCNL).[1] As a result of these advances, together with the popularization of the technique through residency and postgraduate training programs, most urologists now recommend PCNL as the first choice for treating large and complex urinary calculi.[2] PCNL usually ends with the placement of a nephrostomy tube to allow for drainage, tamponade of bleeding, and delayed second-look nephroscopy.[3] Placement of a postoperative temporary nephrostomy tube and urinary leakage that persists after its removal, however, remain a significant inconvenience for both patient and medical personnel, increase the analgesic requirement, and prolong the hospitalization.[4,5] In an attempt to avoid this problematic feature, a tubeless approach has been successfully reported in selective groups of patients.[3–10] The present study was designed to assess whether the applicability of tubeless PCNL could be further extended based on intraoperative decision, without preoperative selection.

MATERIAL AND METHODS

The study consisted of a consecutive and prospective series of 126 patients presenting for PCNL during a 2-year period, starting January 2004. After providing written informed consent, all patients were considered for tubeless PCNL without any preoperative selection. The institutional review board representative had ruled that no institutional review board approval was needed because the study was not randomized, all the performed procedures represented well-established and commonly practiced operations, and no experimental elements were included. Prophylactic perioperative wide-spectrum antibiotics were administered to patients with sterile urine, and patients with bacteriuria were treated according to the antibiogram results.

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The preoperative stone burden was calculated as the area measured on digital radiography and computed tomography by calibrated software.

Access was performed in the operating room by the endourologic team. Under general anesthesia, patients were placed in the prone position to allow for simultaneous access to the flanks and perineum. Fluoroscopic control and guidance were achieved using a C-arm mobile x-ray machine (Siremobil Compact, Siemens, Erlangen, Germany) and a regular operating room table with a fluoroscopic extension (Endostar, Maquet, Rastatt, Germany). Using a flexible cystoscope, a floppy tip guidewire, followed by a 5F open-ended ureteral catheter, were retrogradely inserted up to the ureteropelvic junction. The intrarenal collecting system was fluoroscopically visualized using contrast material, and the triangulation maneuver was used to achieve renal access. The tract was dilated up to 20F to 30F using either Amplatz sequential dilators (Cook Ireland, Limerick, Ireland) or NephroMax balloons (Boston Scientific Ireland, Galway, Ireland). Fragmentation and stone removal were accomplished in all patients using pneumatic and ultrasound energy and retrieval graspers through rigid 18F to 26F nephroscopes. A holmium laser and tipless nitinol basket were used through flexible nephroscopes for locations unreachable using the rigid instruments. At the end of the procedure, a 7F internal double-J stent was placed in an antegrade manner. Contrast nephrography, flexible nephroscopy, backward endoscopic surveillance of the working tract, and hemodynamic assessment were used to rule out perforation, residual stones, and active bleeding. The patients were then left without a nephrostomy tube, and the wound was either tied or sealed with Dermabond (2-octyl cyanoacrylate).[11] Alternatively, a 16F Foley catheter was used as a nephrostomy tube in patients suspected of having significant perforation, residual stones, and/or bleeding. For postoperative analgesia, the patients were given intramuscular pethidine HCL (Dolestine) (1 mg/kg) every 6 hours on request. The stone-free status was evaluated on the morning after the procedure by unenhanced computed tomography (CT) on a 16-slice multidetector CT scanner (MX 8000 IDT, Philips Medical Systems, Cleveland, Ohio). Patients with residual fragments after regular PCNL underwent second-look PCNL, in the endoscopic suite, using the preexistent tract without anesthesia. Patients who underwent tubeless PCNL and had residual fragments were referred for ancillary procedures (eg, shock wave lithotripsy, ureteroscopy).

The regular and tubeless PCNL groups were compared statistically in terms of demographics, clinical features, intraoperative technical aspects, postoperative course, hospitalization, and recovery. The analysis was conducted using statistical software.

The follow-up evaluation was performed 2 to 3 months after the operation and consisted of an assessment of symptoms, a clinical examination, the determination of renal functionality and urinary tract patency, urine culture, and an evaluation for metabolic disorders. In addition, stone-free status was reevaluated by CT in patients who had not been stone free on the CT scan performed immediately after the operation.

RESULTS

Using the study protocol, we performed 66 (52%) tubeless and 60 (48%) regular PCNLs. The groups were similar in terms of demographic and clinical data, as well as access position and method of tract dilation (Table 1).

The median operative time was 115 and 120 minutes and the immediate stone-free rate was 92% and 90% for the tubeless and standard PCNL groups, respectively ($P > 0.05$). Residual stones were identified in 5 patients after the tubeless procedure: 2 were referred for shock wave lithotripsy and 3 for retrograde intrarenal surgery. An ancillary procedure was needed in 6 patients in the standard group: 4 were treated with shock wave lithotripsy and 2 with retrograde intrarenal surgery. The average residual stone burden was 52 mm^2 (range, 30 to 100 mm^2) and 49 mm^2 (range, 30 to 81 mm^2) for the tubeless and standard PCNL groups, respectively ($P = 0.88$).

Standard PCNLs were performed because of an expected second-look procedure in 35 (58%) patients, an impression of active bleeding in 16 patients (27%), significant extravasation in 5 patients (8%), and suspected hydrothorax in 4 patients (7%). We performed 17 second-look procedures (28%) within 2 days of the initial standard PCNL, at nephrostomy tube removal, with no anesthesia or repeat dilation of the tract. Six of these procedures revealed residual stones. They were considered a complementary part of the initial PCNL and, consequently, the 90% stone-free rate reported for the standard PCNLs was calculated after these second-look procedures. The postoperative course was characterized by nonsignificant average changes in the creatinine and hemoglobin levels for both groups ($P > 0.05$). The median analgesic requirement was 0.4 and 1.3 mg/kg pethidine HCL for the tubeless and standard PCNL procedures, respectively ($P < 0.01$). The median hospitalization and recovery time in the tubeless PCNL group were significantly shorter than for the standard PCNL group (1 versus 4 days, $P < 0.0001$, and 7 versus 20 days, $P < 0.001$, respectively). The overall complication rate was 9% in the tubeless group and 13% in the standard group ($P > 0.05$). A postoperative decrease in the hemoglobin concentration requiring blood transfusion occurred in 1 tubeless and 2 standard patients (2% for the whole series). Of these patients, 1 in each group required a blood transfusion with the initiation of full anticoagulant therapy because of postoperative pulmonary emboli. Tubeless PCNL complications also included urinary tract infection in 2 patients (one immediate and one late), pulmonary emboli in 1, hydrothorax in 1, and pleural empyema in 1. The complications in the standard group also included urinary tract infection in 2 patients (both immediate), prolonged tract leakage in 1, pulmonary emboli in 1, hydrothorax in 1, and pleural empyema in 1. No other complications had occurred after a median follow-up of 13 months (range, 3 to 24 months).

The assessment of the rate of tubeless PCNLs performed by us over time revealed a steady increase from 38% in the first half year to 80% in the last half year of the study ($P < 0.01$; Table 2).

COMMENT

In recent years, interest has been evolving in the search for refinements of percutaneous procedures. The research

Table 1. Demographic and clinical data of study groups

Criteria	Tubeless PCNL (n = 66; 52%)	Standard PCNL (n = 60; 48%)	*P* Value
Age (yr)			0.5
Average	54	52	
Range	28–82	2–86	
Median	53	54	
BMI (kg/m^2)			0.5
Average	29	28	
Range	21–46	21–44	
Median	28	28	
Stone burden (mm^2)			0.3
Average	924	1044	
Range	400–3150	225–2800	
Median	700	750	
Male/female ratio	1.3 (37/29)	1.5 (36/24)	0.6
Right/left ratio	0.9 (31/35)	0.8 (27/33)	0.76
Anatomic anomaly (n)			
Solitary kidney	3	2	0.7
Horseshoe kidney	1	1	0.94
Duplex system	2	0	0.17
Caliceal diverticula	3	3	0.95
Total	9 (14)	6 (10)	0.55
Previously operated kidneys (n)	10 (15)	10 (17)	0.84
Staghorn stones (n)	26 (39)	28 (47)	0.35
Access (n)			
Supracostal	21* (32)	23† (38)	0.36
Multiple (≥2)	5 (8)	6 (10)	0.42
Dilation			0.5
Sequential tract	50 (76)	42 (70)	
Balloon tract	16 (24)	18 (30)	

PCNL = percutaneous nephrolithotomy; BMI = body mass index.
Data in parentheses are percentages, unless otherwise noted.
* Seven supracostal XI.
† Eight supracostal XI

Table 2. Percentage of tubeless PCNLs performed over time

Period	Tubeless PCNL (%)	Standard PCNL (%)	Total	*P* Value
January–June, 2004	12 (38)	20 (62)	32	—
July–December, 2004	23 (49)	24 (51)	47	0.3
January–June, 2005	15 (56)	12 (44)	27	0.16
July–December, 2005	16 (80)	4 (20)	20	0.003
Total	66 (52)	60 (48)	126	—

PCNL = percutaneous nephrolithotomy.

has focused on decreasing the trauma to the kidney and the percutaneous tract, as well as reducing postoperative morbidity, analgesia requirements, hospital stay, and cost. One of the clinically tested modifications is the minipercutaneous approach.[12–14] First reported by Jackman *et al.*[12] in pediatric patients, minipercutaneous PCNL, using 13F to 20F working sheaths, was soon adapted to adults and resulted in reduced operative times, less postoperative morbidity, and a hospital stay of 1.1 days.[13] This miniaturized procedure, however, still ended with placement of a nephrostomy tube. Together with its advantages in providing drainage, tract tamponade, and maintenance of access for second-look procedures, the nephrostomy tube is also associated with postoperative pain. Addressing this issue, Pietrow *et al.*[14] showed that the use of a narrower tube (10F instead 22F) can improve comfort in the immediate postoperative period without sacrificing safety. Kim *et al.*[15] analyzed a series of 106 renal units treated for complex stones and concluded that the size, location, and type of postoperative drainage should be selectively tailored and that 8.5F to 10F Cope loop catheters should be used for most cases. Another major inconvenience related to the use of nephrostomy tubes is urinary leakage persisting sometimes longer than 24 hours after tube removal. This can be avoided by immediate wound sealing using tissue adhesives when postoperative renal obstruction has been excluded.[11]

A new alternative has joined these trials to miniaturize the procedure and to choose the most suitable external drainage: the concept of the tubeless technique. Revived and refined by Bellman *et al.*[4] in 1997, this approach involves the internalization of the postoperative renal drainage by placement of an internal stent and bladder catheter, instead of the traditional externalized flank tube. The investigators reported their initial experience with a series of 50 patients who had undergone various percutaneous procedures. Of the 50 patients, 30 were left with a nephrostomy tube in place for 2 to 3 hours and 20 were not given any flank drainage. Comparing that series with a matched group of 50 standard PCNLs, the investigators demonstrated a significant reduction in hospitalization, recovery time, analgesic requirement, and treatment-related cost.[6] Five years later, Limb and Bellman[3]

concluded 112 successful tubeless procedures, representing almost one third of their total number of percutaneous procedures. Prospective randomized studies designed to compare tubeless versus mini versus standard PCNL have confirmed the superiority of tubeless PCNL in terms of less postoperative patient discomfort, shorter hospitalization, and a speedier recovery.[7,8] The recognition of these advantages encouraged the endourologic community to search for additional applications of the technique. In a series of 43 patients, Aghamir *et al.*[9] reported that totally tubeless PCNL is feasible and more advantageous than standard PCNL, and Shah *et al.*[10] successfully performed bilateral simultaneous tubeless PCNL in a series of 10 patients. To the best of our knowledge, however, all tubeless PCNL studies reported to date were performed on selected patients. The selection criteria varied from study to study and included normal anatomic and functional kidneys, not previously operated kidneys, a stone burden less than 3 cm, an operative time shorter than 2 hours, a subcostal approach, and no more than two accesses.[3–10]

Our previous experience with tubeless procedures had been limited, and we had adopted the criteria mentioned in these cited reports. Our present study represents an additional step toward the extension of tubeless PCNL applicability. All our patients were considered for tubeless PCNL without any preoperative selection. This meant including solitary, anomalous, and previously operated kidneys, multiple and supracostal accesses, complex and large stones, and lengthy operations. Despite these challenging circumstances, more than one half of our patients could be treated using the tubeless approach. Furthermore, our ability to apply this approach improved steadily with time, reaching a rate of more than 80% of all procedures performed in the last half year of study, possibly reflecting a learning curve.

We believe that two main concerns could still preclude the accomplishment of tubeless PCNL: residual stones and significant bleeding. Our 92% stone-free rate, as demonstrated by immediate postoperative CT scanning, appears to indicate an accurate intraoperative assessment of residual stones. In 35 of our standard PCNL patients, however, we left a nephrostomy tube in place, expecting the necessity of a second-look procedure. This expectation was determined by either suboptimal endoscopic surveillance of the entire collecting system with the flexible nephroscope (eg, clots, bleeding, inaccessible calices) or the radiolucent characteristics of the stone that limited its detection by intraoperative fluoroscopy. Residual fragments were demonstrated on the postoperative CT scan in one half of these patients, but these fragments were detected during the second-look procedure in only 6 cases. Such discrepancies between the CT scan findings and flexible nephroscopy findings was analyzed by Pearle *et al.*[16] They reported a sensitivity of 62% only when CT scanning was performed to assess for residual fragments before second-look nephroscopy and stated that selective use of flexible nephroscopy after PCNL on the basis of positive CT findings will avoid an unnecessary operation in only 20% of patients. Another possible explanation of the reduced number of positive findings on second-look nephroscopy in our study was that the procedures were performed 1 day after the CT scan, sufficient time for small fragments to have been spontaneously evacuated.

Portis *et al.*[17] recently reported improved intraoperative detection of residual stones when performing PCNL in the interventional radiology suite using combined flexible nephroscopy and high-magnification rotational fluoroscopy. Comparing that method with the use of postoperative CT scans, their initial results revealed a sensitivity, specificity, negative predictive value, and accuracy of 100%, 95%, 100%, and 96%, respectively, in detecting fragments larger than 4 mm. Such an approach could contribute to increased tubeless PCNL applicability and better stone-free rates, but it would necessitate accessibility to an advanced interventional fluoroscopic machine, possible only at a very limited number of institutions at present. Borin *et al.*[18] reported on treating posttubeless PCNL residual stones using outpatient ureteroscopy at internal stent removal. The question of whether this approach is preferable to standard PCNL and second-look nephroscopy remains to be elucidated in clinical trials. The other main intraoperative problem, the evaluation of bleeding severity, is dependent on a clinical assessment of the patient's hemodynamic status and the surgeon's experience. In our present study, we did not encounter any situations of hemodynamic instability, although one quarter of the standard PCNLs were performed because of the surgeon's impression of active bleeding. One of the main issues that apparently influenced the learning process and, finally, the learning curve throughout this study was becoming familiar with the presence of bloody discharge at the wound site after removal of the working sheath and recognizing that this bleeding is not clinically significant and usually ceases spontaneously within a few minutes. As such, we came to understand that we could avoid the placement of a nephrostomy tube in most cases. The low overall transfusion rate (3%), which mostly resulted from the institution of anticoagulant therapy, raises the question of whether the nephrostomy tube played a major role in stopping the bleeding or whether the surgeon had overestimated the extent of bleeding, which might have ceased spontaneously in most cases. Similar clinical observations have lately led to a search for solutions to actively stop the bleeding and avoid the placement of a nephrostomy tube in patients rendered stone free. Sealant hemostatic materials, such as fibrin glue and gelatin matrix, have been shown to efficiently and safely control the bleeding.[18,19] Despite their advantages, we refrained from using hemostatic sealants because of cost restraints. Another tool that has been shown to adequately stop

bleeding points along the tract is endoscopic electrofulguration.[20] This option could also play a positive role in expanding the number of cases suitable for tubeless PCNL.

CONCLUSIONS

Our results have attested that tubeless PCNL can be safely and effectively performed without preoperative contraindications. The intraoperative assessment is accurate enough to achieve results as good as those with the standard technique. By confirming the advantages of the tubeless technique in terms of postoperative patient discomfort, hospitalization, and recovery, we believe that this study represents another contribution to the further popularization of the tubeless technique.

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EDITORIAL COMMENT

The authors present a large series of patients who underwent PCNL. At the conclusion of the procedure, a decision was made regarding the necessity of nephrostomy tube placement that was not determined by preoperative criteria of stone size or patient characteristics, but on the surgeon's impressions of trauma or residual stone fragments. During the study period, as the authors grew more confident in stone clearance and tolerant of bleeding, the rate of tubeless procedures increased from 38% to 80% of otherwise unselected patients.

The essential decision of when to place a nephrostomy tube remained subjective and based on clinical judgment. However, good judgment is the product of experience, which itself is the product of bad judgment. The adoption of tubeless PCNL in other centers would be facilitated, and patients spared the exposure to an unnecessary surgical learning curve, if objective criteria for decision making could be established.

The most common reason for placing a nephrostomy tube was suspicion of residual calculi. Stone clearance was evaluated in all patients with noncontrast CT. Of 35 patients with suspected residual calculi, second-look nephrostomy was performed in 17, with stone fragments removed in just 6 cases. The likelihood that the suspicion of residual calculi would be confirmed at the second-look procedure is measured by a positive predictive value of just 18%. Although the authors cited the landmark study of Pearle *et al.*[1] as a precedent for such a low yield, it must be noted that in the latter study, the results were based on an absolute interpretation of the CT findings, such that "stone free" truly meant no detectable fragments.

It is essential to focus discussions of stone treatment procedures on stone clearance efficacy. The authors failed to define their interpretation of "stone free." Among the patients not considered "stone free," additional procedures were performed for stones of 30 to 100 mm^2, which corresponds to an axial dimension of 5 × 6 to 10 × 10 mm. Apparently, either no stone fragments of 4 mm or less were found on CT or "stone free" was defined with respect to a 4-mm threshold. Therefore, the stated single-procedure "stone-free" rate was not 92% and 90% for the tubeless and regular PCNL groups, respectively. One could estimate that the true stone-free rate for the 60 patients in the regular PCNL group would not include the 17 patients who had CT scan findings that prompted second-look nephroscopy or the 6 patients who required an additional procedure, which would yield a single-procedure rate of less than 62%.

The authors are to be commended on enlarging the popula-